PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	Boyce
Serial Number	10/092,237
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Confirmation No.	8680
Art Unit	1633
Examiner	Kaushal
Title	**SURGICAL DEVICE FOR SKIN THERAPY OR TESTING**
Attorney Docket No.	074057.7

Cincinnati OH 45202 April 23, 2009

DECLARATION OF STEVEN T. BOYCE, Ph.D.

1. I am the inventor in the referenced application.

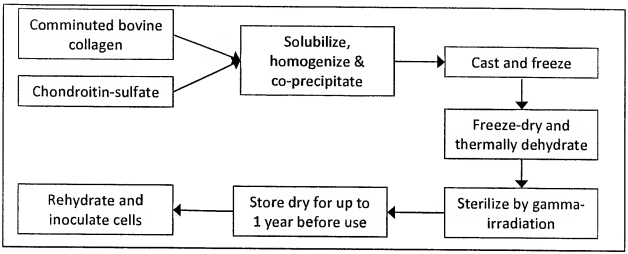
2. I received my Doctor of Philosophy degree from the University of Colorado, in the field of molecular, cellular, and developmental biology. I have 34 years of experience in biomedical research, 26 of which are in the field of skin science research, the subject of this application.

3. I attended the February 3, 2009 Oral Hearing and, at the Board's invitation, participated in the Hearing.

4. I have amended all claims to further clarify ways in which my claimed method is distinguished from, and thus does not anticipate, the method disclosed in Krejci et al., J. Invest. Dermatol. 97 (1991) 843.

5. My amended claims clarify that my matrix is prepared by casting, freezing, and dehydrating a collagen-containing solution. I have shown these steps schematically in the following diagram:

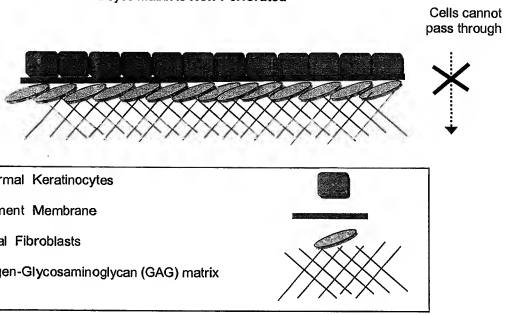
Boyce Matrix is **"Prepared From A Matrix-Forming Collagen Containing Fluid** That Is **Cast, Frozen, and Dehydrated"**



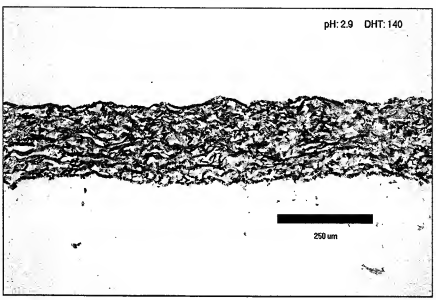
The comminuted bovine collagen and chondroitin-sulfate are solubilized, homogenized, and co-precipitated. Casting and freezing regulates the thickness of my matrix, and regulates the spacial distribution of polymers in my matrix. Drying permits long term storage of my matrix, one year or even longer. The total time to prepare my matrix is less than one week.

6. My amended claims clarify that my matrix is non-perforated. I have shown this both schematically in cross section as follows:

Boyce Matrix is **Non-Perforated**



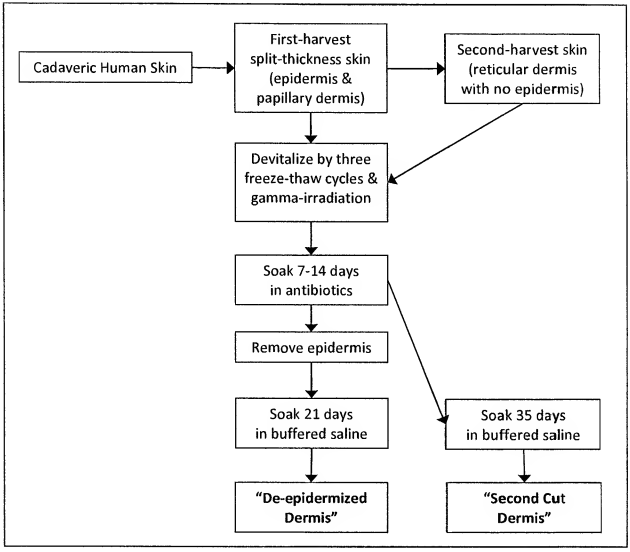
and in a histologic cross section of the acellular matrix as follows:



My non-perforated matrix does not allow passage of cells across its thickness. When cells are inoculated, the cells cover the matrix to immediately form a surface lamination.

7. Krejci's matrix, in contrast, is prepared from processed cadaver tissue. I have shown this schematically in the following diagram of Krejci's matrix preparation.

Krejci's Matrix is **NOT " Prepared From A Matrix-Forming Collagen Containing Fluid** That Is **Cast, Frozen, and Dehydrated"**:



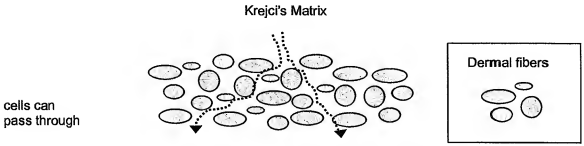
Krejci's matrix uses, as the starting material, human skin obtained from a cadaver. In contrast, I use, as the starting material, comminuted bovine collagen and chondroitin-sulfate obtained from a commercial vendor.

Krejci does not prepare a matrix from solubilized collagen to result in a "collagen-containing fluid", as I claim.

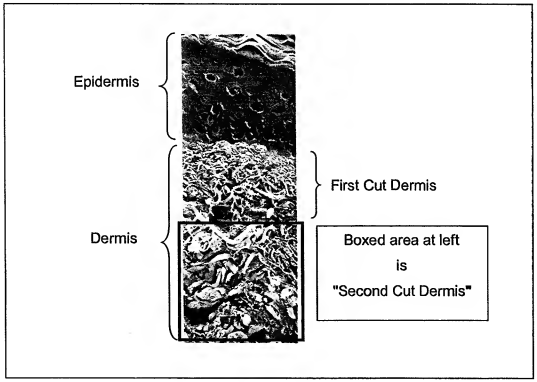
Krejci does not use a fluid that is "cast, frozen, and dehydrated", as I claim.

Krejci's overall process prepares a matrix by destroying a natural tissue. Krejci's matrix is not "prepared from a matrix-forming collagen-containing fluid" and does not result in a "device", as I claim.

8. Krejci's matrix, in contrast, is perforated, and cells can pass through.



In cross-section, Krejci's matrix has contiguous channels across its thickness that are sufficiently large in diameter to allow cells to pass into and through the matrix (arrows). A natural dermal matrix, e.g., Krejci's matrix, has the following structure shown in the boxed area of the micrograph below:



My claimed matrix and Krejci's matrix have very different physical properties, e.g., Krejci's matrix has different tensile strength, a different mass/unit volume, and a different biologic degradation time compared to my claimed matrix.

9. Krejci's resulting apparatus requires more than four weeks to prepare. Based on Krejci's protocol, Krejci harvests reticular dermis that must be soaked in antibiotic 7-14 days, and must be soaked in buffered saline 21-35 days. In contrast, using my matrix to prepare my device, dermal cells provide "a cellular lamination layer within a shorter time period than is possible using a perforated matrix", as I claim, because dermal cells, not being able to go through my non-perforated matrix, immediately form "a cellular lamination layer" upon inoculation.

10. In my opinion, in at least these embodiments, each of which I claim, Krejci's matrix differs both in composition and method of preparation from my matrix. I thus respectfully dispute that Krejci anticipates my claimed device or my claimed method.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the subject application or any patent issued thereon.

23 APRIL 2009
Date

Steven T. Boyce, Ph.D.

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